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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/506,766 02/18/00 BEN-HAIM

S BIO-95

EXAMINER

QM12/1025

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OROPEZA, F

ART UNIT

PAPER NUMBER

3762

DATE MAILED:

10/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/506,766

Applicant(s)

BEN-HAIM ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, line 12, "said catheter tip" lacks antecedent basis.

In claim 16, line 10, "the wall" lacks antecedent basis.

In claim 30, line 1, "said electrical characteristics intermediate said" is unclear.

In claim 35, line 9, "the wall" lacks antecedent basis.

In claim 42, line 9, "the wall" lacks antecedent basis.

In claim 47, line 8, "the wall" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 12, 13, 15-18, 22, 32-37, 39-45 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Ben-Haim et al. (US 5718241). Ben Haim et al. disclose a method and apparatus to treat arrhythmias with ablation using one or more catheters (abstract).

The tip of the catheter contains an electrode which can function at a site in the heart to sense electrical cardiac activity, to act as an antenna to deliver radio-frequency energy to perform ablation of tissue, or to deliver stimuli for pacing the heart (column 11, lines 28-35). The electromagnetic location system in the tip of the catheter can contain between one and ten antennas to define the location of the tip area of the catheter (column 11, lines 49-59). In figure 16, a tip electrode (105) and additional electrodes (106), read as an array of non-contact electrodes, are disclosed. The receiving antennas are located near the distal tip of the catheter (column 12, lines 41-47).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 4-6, 14, 19-21, 26-31, 38, 46 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US5718241) in view of Martinelli (US 6104944). As

discussed in paragraph 2 of this action, Ben-Haim et al. disclose the claimed invention except for providing six degrees of location information using locations sensors in a proximate and a distal position relative to the electrode array.

Martinelli discloses a system and method for navigating a multiple electrode catheter and teaches that it is known to use two or more navigated electrode elements (N1-Nn), read as location sensors, between multiple virtually navigable electrode elements (E1-En), read as an array of non-contact electrodes (column 4, line 66 – column 5, line 8 and column 5, lines 24-33) to define the position of electrodes in a domain such as a chamber of the heart (column 4, lines 63-66). Martinelli teaches the use of electromagnetic field sensors as the navigated electrode elements to provide navigational location information (column 6, lines 18-32). These navigated electrode elements provide orientation data and position coordinate data, read as the six degrees of location information (column 6, lines 54-64 and column 8, lines 29-65), to establish the location of the virtually navigated electrodes and enable accurate mapping of the heart.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, providing six degrees of location information using location sensors in a proximate and a distal position relative to the electrode array as taught by Martinelli to enable accurate mapping of the heart so arrhythmia producing cardiac tissue is identified and can be ablated.

5. Claims 8, 11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim (US 5718241) in view of Swanson et al. (US 6171306). As discussed in paragraph 2 of this action, Ben-Haim discloses the claimed invention except for the distal tip contact electrode

being a bipolar electrode. Swanson et al. disclose an ablation catheter and teach that it is known to use a bipolar distal tip electrode to ablate the cardiac tissue (figure 5, and column 7, lines 11-14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, with a bipolar distal tip electrode as taught by Swanson et al. to utilize the electrodes in the device, the tip and the array electrodes, to ablate the tissue, eliminating the need for the addition of an external indifferent electrode (column 7, lines 17-20). Utilizing a bipolar configuration also provides a more targeted ablating stimulus enabling more precise ablation.

6. Claims 9, 10, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim (US 5718241) in view of Kagan et al. (US 5311866). As discussed in paragraph 2 of this action, Ben-Haim discloses the claimed invention except for the electrode array comprising about twelve to about thirty-two or about sixteen to about twenty-four electrodes. Kagan et al. disclose an heart mapping catheter and teach that it is known to use an array of between twenty-four and sixty four electrodes to map the electrical activity of the heart (column 3, lines 25-29). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, with an array of about twenty-four electrodes as taught by Kagan et al. to enable sufficient contact between the electrode array and the cardiac tissue to gain a clear understanding of the electrical activity of the heart so appropriate ablation treatment could be performed.

Other Prior Art Cited

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6272371 to Shlomo teaches position sensors in a catheter. US 5938602 to Lloyd teaches monitoring the position of a catheter head.

Conclusion

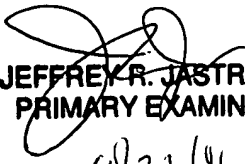
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO


JEFFREY R. JASTRZAB
PRIMARY EXAMINER
10/22/01